General Assembly

Raised Bill No. 5307

February Session, 2010

LCO No. **1425**

*01425_____PH_*

Referred to Committee on Public Health

Introduced by:
(PH)

AN ACT CONCERNING THE FILLING OF PRESCRIPTIONS FOR ANTIEPILEPTIC DRUGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-619 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2010*):

(a) For the purposes of section 20-579 and this section:

(1) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug product, its container, label or wrapping at the time of packaging;

(2) "Generic name" means the established name designated in the official United States Pharmacopoeia/National Formulary, official Homeopathic Pharmacopoeia of the United States, or official United States adopted names or any supplement to any of them;

(3) "Therapeutically equivalent" means drug products that are approved under the provisions of the federal Food, Drug and Cosmetics Act for interstate distribution and that will provide essentially the same efficacy and toxicity when administered to an

individual in the same dosage regimen; **[**and**]**

(4) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to, tablets, capsules, oral solutions, aerosol, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of any physical formulation or medium that uses a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body;

(5) "Epilepsy" means a neurological condition characterized by recurrent seizures;

(6) "Seizures" means a disturbance in the electrical activity of the brain; and

(7) "Antiepileptic drug" means a drug prescribed for the treatment of epilepsy or a drug used to prevent seizures.

(b) Except as limited by subsections (c), **[**and**]** (e) and (i) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a generic name drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent. When the prescribing practitioner is not reasonably available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.

(c) A prescribing practitioner may specify in writing or by a telephonic or other electronic communication that there shall be no

substitution for the specified brand name drug product in any prescription, provided (1) in any prescription for a Medicaid, state-administered general assistance, or ConnPACE recipient, such practitioner specifies the basis on which the brand name drug product and dosage form is medically necessary in comparison to a chemically equivalent generic name drug product substitution, and (2) the phrase "BRAND MEDICALLY NECESSARY", shall be in the practitioner's handwriting on the prescription form or on an electronically-produced copy of the prescription form or, if the prohibition was communicated by telephonic or other electronic communication that did not reproduce the practitioner's handwriting, a statement to that effect appears on the form. The phrase "BRAND MEDICALLY NECESSARY" shall not be preprinted or stamped or initialed on the form. If the practitioner specifies by telephonic or other electronic communication that did not reproduce the practitioner's handwriting that there shall be no substitution for the specified brand name drug product in any prescription for a Medicaid, state-administered general assistance, or ConnPACE recipient, written certification in the practitioner's handwriting bearing the phrase "BRAND MEDICALLY NECESSARY" shall be sent to the dispensing pharmacy within ten days.

(d) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE." The printing on the sign shall be in block letters not less than one inch in height.

(e) A pharmacist may substitute a drug product under subsection (b) of this section only when there will be a savings in cost passed on to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

(f) Except as provided in subsection (g) of this section, when a

pharmacist dispenses a substitute drug product as authorized by subsection (b) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug product. If the dispensed drug product does not have a brand name, the prescription label shall indicate the generic name of the drug product dispensed along with the name of the drug manufacturer or distributor.

(g) A prescription dispensed by a pharmacist shall bear upon the label the name of the drug in the container unless the prescribing practitioner writes "DO NOT LABEL", or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

(h) Neither the failure to instruct by the purchaser as provided in subsection (b) of this section nor the fact that a sign has been posted as provided in subsection (d) of this section shall be a defense on the part of a pharmacist against a suit brought by any such purchaser.

(i) Upon the initial filling or renewal of a prescription that contains a statistical information code based upon the most recent edition of the International Classification of Diseases indicating the prescribed drug is used for the treatment of epilepsy or to prevent seizures, a pharmacist shall not: (1) Substitute for the prescribed drug another antiepileptic drug or formulation of another antiepileptic drug, irrespective of whether such other antiepileptic drug is a brand name drug product or a generic name drug product, and (2) fill the prescription by using a new drug manufacturer or distributor of the prescribed drug, unless the pharmacist provides prior notice of such substitution or use of a new drug manufacturer or distributor to, and obtains the written consent of, the patient's practitioner. For purposes of obtaining the consent of the patient's practitioner required by this subsection, a pharmacist shall notify the patient's practitioner via electronic mail or facsimile transmission. If the patient's practitioner does not provide the necessary consent, the pharmacist shall fill the

prescription without such substitution or use of a new drug manufacturer or distributor or return the prescription to the patient or to such patient's representative for filling at another pharmacy. If a pharmacist is unable to contact the patient's practitioner after making reasonable efforts to do so, such pharmacist may exercise professional judgment in refilling a prescription in accordance with the provisions of subsection (b) of section 20-616. For purposes of this subsection, "pharmacy" means a place of business where drugs and devices may be sold at retail and for which a pharmacy license was issued pursuant to section 20-594, including a hospital-based pharmacy when such pharmacy is filling prescriptions for employees and outpatient care, and a mail order pharmacy licensed by this state to distribute in this state. "Pharmacy" does not include a pharmacy serving patients in a long-term care facility, other institutional facility or a pharmacy that provides prescriptions for inpatient hospitals.

[(i)**]** (j) The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2010*	20-619

Statement of Purpose:

To prohibit a pharmacy upon the initial filling or renewal of a prescription for the treatment of epilepsy or prevention of seizures from substituting an antiepileptic drug or formulation of an antiepileptic drug for the prescribed drug without first obtaining the consent of the patient's practitioner to make such substitution.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]